iii) generating assay information relating to said sample; and

iv) recording the assay information via the recording part of the assessment device.

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39. A kit comprising an assessment device according to any preceding claim comprising an assessment device, assay reagents and protective packaging for transport of the recording device to a processing facility.

Remarks

The Office Action dated February 9, 2000 has been read and carefully considered and the present amendment submitted in order to clarify the claim language describing the invention to better define that invention. Initially, it is noted that an objection was made to the absence of an Abstract and, accordingly, an Abstract is submitted herewith as a new page 17 to be added following the claims. Objections were also made to the drawings and corrected drawings are submitted herewith for the review and approval of the Examiner with the corrections in red showing the Figure numbers for Figures 1-3.

In the aforesaid Office Action, claims 1-19 were rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. As such, therefore, all of the former claims have been canceled and new claims 20-39 submitted. It is believed that the newly submitted claims have been written to correct the claim language as to indefiniteness and that the new claims now are in compliance with 35 U.S.C. 112, second paragraph.

In particular, Claim 1 has been amended and resubmitted as claim 20 to clarify the relationship between the two parts, and in particular, to deal with the objection relating to the use of "adapted to" wording in the claim language. A similar change has been made to the newly submitted claim 22 to deal with the same objection that was made with respect to the prior claim 3. All of the new claim language has a basis in the specification and thus, no new matter has been introduced.

In response to the Examiner's objection to the language of claim 2, (now claim 21) additional structure has been added to describe the feature of prior claim 2 to describe the recording part as "small and light" based upon the disclosure in the specification, page 4. In addition, those objected claims based upon the alternative phrase "and/or" have been corrected by, in the case of claim 2 (now claim 21), omitting that alternative language, and with respect to claim 15 (now claim 35), by substituting alternative language and in claim 17 (now claim 37), by using the word "results" which, is submitted, would be readily understood by one skilled in the art to which this invention pertains to be equivalent in the earlier text.

A new claim 24 is added in a more generalized language for that of prior claim 5 and, in turn, claim 5 has been submitted as new claim 25 dependent upon claim 24, again based upon the specification, page 5, to state that the recording device is an electronic data storage device. The subsequent claims have been renumbered and resubmitted. The prior claim 18 has been rewritten and submitted herewith as claim 38 and has been expanded to include an information generation step as suggested by the Examiner.

Turning to the prior art rejection, Claims 1-19 were further rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al (U.S. Patent 4,756,884 and 4,963,498) in view of Galen et al (U.S. Patent 5,695,949) or Phillips et al (U.S. Patent 5,179,005 and 5,426,032). As now worded, it is believed that the rejection has been overcome with the newly submitted claims that better define the present invention.

In particular, the Hillman et al reference was relied upon for disclosing a capillary flow device for performing an analysis which is considered to be broadly equivalent to the assay part of the present invention. The Examiner then suggests that Hillman et al differs "from the claimed invention because they do not disclose an electronic recording device in data communication with the assay device" and thus, further suggests that the Galen et al or Phillips et al devices may be resorted to in order to modify the Hillman et al reference to render Applicant's invention as obvious "because the microprocessor has the well known advantage of large memory storage capacity and fast data processing".

As now more clearly set forth in the claim language, the rejection based upon the aforementioned grounds is submitted to not be applicable and an important and substantial feature of Applicant's invention has now been emphasized to more clearly define the present invention over the cited references.

Specifically, with the present invention, the assessment device comprises an assay part and a recording part which is detachable from the assay part after performing the assay. The detachable nature of the recording part has been emphasized in the new language of the newly submitted claim 20. Provision of a detachable recording part which is in data communication with the assay when

attached, to store the results of at least that assay, but which can be then detached to facilitate subsequent handling of the results, is fundamental to the invention, as is made clear, for example, by lines 17-22 of page 3 of the specification, as filed. It is the detachable nature of the recording part that confers the advantages outlined in the introductory part of the description, in particular in relation to the onward transmission of recorded data for subsequent analysis at a remote site, either by physical transmission of the recording part or by electronically downloading of data from the recording part to a remote analysis center.

In particular, the invention confers the following advantages:

i. A simple to use home or small clinic test not requiring clinical expertise at the sampling site;

ii. The test result is not generated on the device and is not presented or displayed directly to the user (since the device has no facilities for this) which in many cases will be desirable;

iii. The detachable memory chip or other storage stores only raw test signals and clinical results can only be generated once the raw data is processed by the appropriate system at a remote site; this offers opportunities for protection of both patient and commercial confidentiality in relation to the testing system;

iv. Excluding processing and resolved presentation facilities from the devices makes the device less expensive and simple.

In the aforesaid Office Action, the Examiner appears to be under the impression that claim 20, in particular, covers the mere use of a microprocessor in the analysis of assay data. Such a broad interpretation is not justified. The claim, as now presently drafted, is clearly directed specifically to an assessment device comprising two elements, an assay part to perform the test, and a recording part which is attached to the assay part to collect data from the assay part resulting from the test and subsequently detachable for onward transmission of the data for analysis. This recording part cannot be said to be suggested by Galen et al or Phillips et al.

In both Galen *et al* and Phillips et al, there are actually two devices that carry out the assay procedures, that is, a first disposable assay test strip, containing reagents, which the user must insert into the second, or reusable meter or reader. To the contrary, the present invention is a single device as provided to the user that is broken into two parts, and a disposable assay part the a recording part which is detached from the assay part and removed to a remote location where the data can be processed.

In all of these cited references, a simple strip test for blood glucose is described. In each case, the strip comprises various reagents, such that the application of a blood sample to a sampling part of the strip produces a readable, diagnostically significant color profile in readable part of the strip. In each of the three documents cited by the Examiner, this result may then be analyzed by mean of an arrangement of light detector and microprocessor. Thus, it is in the analysis step that the microprocessor becomes significant in the prior art references.

Contrary to the Examiner's suggestion, the present invention does not make use of the "well known advantage of the large memory capacity and fast data processing" on a microprocessor in the detachable recording device. In the preferred embodiment, the detachable recording device is an electronic storage device such as a microprocessor, but this is primarily to facilitate data communication between the storage device and the remote analysis device since it is likely that the remote analysis device itself will be a computer of some description. Even in the case of the preferred embodiment where the storage device is a chip, the chip is intended to store only one set or a limited number of sets of assay data. The assessment device of the present invention does not require, nor is it likely to have, a large memory storage. In addition, the present electronic storage device does not perform any of the analysis and, accordingly, does not require a fast data processing capability.

It is helpful to view the medical assay analysis as comprising three fundamental steps. The first step is the assay step. The second step is the provision of some means to record the raw data resulting from the assay. The third step is the analysis of that data to produce a medically significant diagnostic result. As the present invention makes clear, it is specifically directed to deal with the circumstances where it might be difficult or undesirable to carry out the third step at the time of the testing and, thus, a detachable recording part, or device, is provided at the end of the second step for onward transmission (either physically or electronically) to an analysis site to produce a diagnosis.

On a proper analysis in the context of the invention as above, it is clear that Galen et al and Philips et al do not disclose a detachable electronic recording part to record the data produced by the assay. To the extent that the disclosures of Galen et al and Phillips et al could be said to comprise an assay part and recording part, then

those parts constitute respectively, the sampling and reading zones of the strip. Thus, the recording part of these devices neither stores data electronically, nor is it detachable to allow onward transmission of the data to a remote site.

The prior art relied upon by the Examiner carries out the third, data analysis and diagnostic step electronically via the light transmitter and detector to a central processor. It is submitted that such disclosure is not suggestive at all of the present invention. Indeed, the present invention also envisages, and presents as a preferred option (for example, at page 4, lines 12-17) that the analysis of the data in the recording part would be carried out in this electronic manner.

The Applicant consider that there is a fundamental distinction between the prior art of record and the present invention in relation to the provision of a detachable recording part for the recordal of raw data generated by the assay part, to facilitate handling of the data for subsequent analysis. Thus, a key feature of the recording part of the present invention, in a preferred embodiment, is that assay data is stored in the recording part electronically. Simply, the recording part is attached to the assay part, data is collected, the recording part is detached from the assay part, and data is transmitted via the recording part to a site for remote analysis.

Accordingly, as now defined in the newly submitted claims, it is believed that the

language now clearly distinguishes the present invention over the cited references such that the claims define a patentable invention over those references, and an allowance of the present patent application is respectfully solicited.

Fees

A check in the amount of $130.00 is included to cover the multiple dependent claim fee. No additional fees are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or to credit any overpayments.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited. Should a discussion aid in the prosecution of the application, the Examiner is invited to telephone the undersigned at (201) 487-5800, to effect a resolution.

Respectfully submitted,
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RECORDING ASSAY DEVICE

Abstract Of The Disclosure

An assessment device comprises an assay part and a recording part wherein the recording part is detachable from the assay part. The assessment device facilitates the rapid assaying and processing of tissue/fluid samples by healthcare workers and the assaying data is stored in the recording part. The assaying data is thus detachable via the recording part from the assay part so that the recording part can be transported to a remote site of processing facility where the assaying data can be interrogated and the analysis completed.

B'

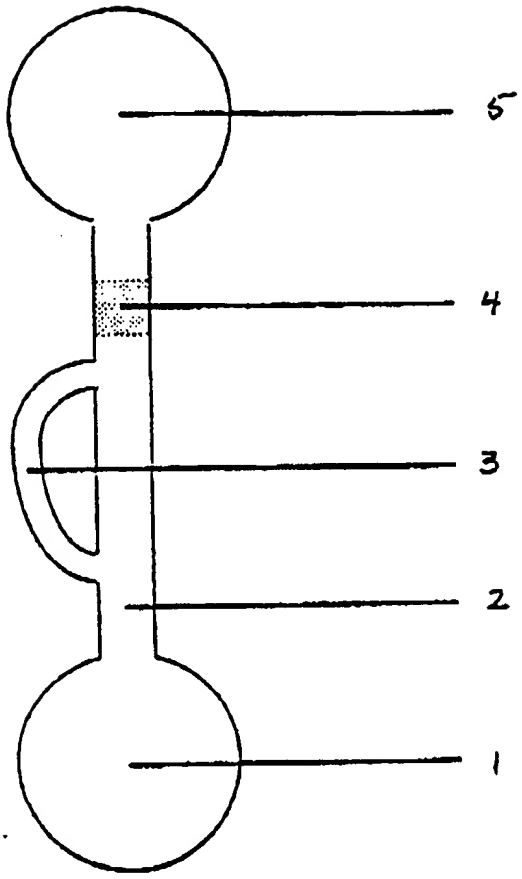

FIG. 1

EXAMPLE - INTERNAL LAYOUT

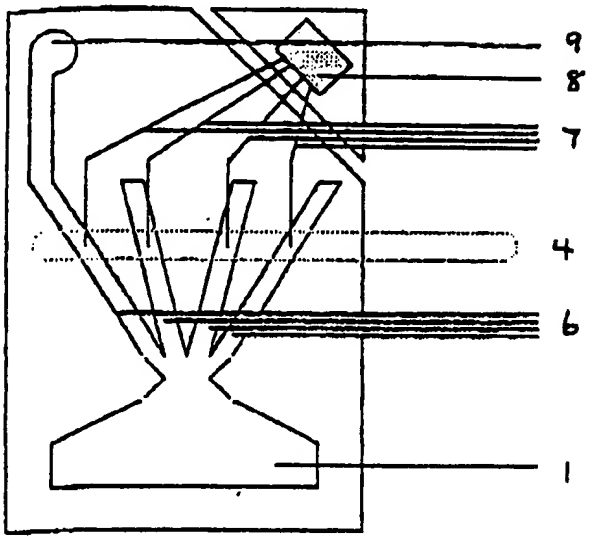

FIG. 2

EXAMPLE - EXTERNAL VIEW

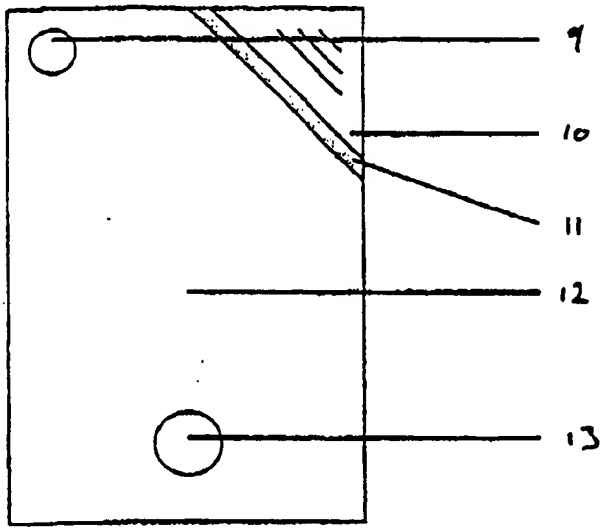

FIG. 3